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09/388,294

FIRST NAMED APPLICANT

ATTORNEY DOCKET NO./TITLE

09/01/99

EVANS

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NOT ASSIGNED

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SAN PRANCISCO CA 9411-3834

09/21/99

NOTICE TO FILE MISSING PARTS OF APPLICATION Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1:136(a). If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of □ \$65.00 for a small entity in compliance with 37 CFR 1.27, or 🖂 \$130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.

If all required items on this form are filed within the period set above, the total amount owed by applicant as a small entity (statement filed) Snon-small entity is
☐ The statutory basic filing fee is: ☐ missing. ☐ insufficient. Applicant must submit \$ 16 (
The following additional claims fees are due: \$\frac{314}{50} \text{ for } \frac{75}{50} \text{ total claims over 20.} \$\frac{78}{50} for
Applicant must either submit the additional claim fees or cancel additional claims for which fees are due. The oath or declaration: Is missing or unsigned. Odes not cover the newly submitted items. An oath or declaration in compliance with 37 CFB 1 63 including residence information and identifying the applicant.
the above Application Number and Filing Date is required. 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:
An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.
 6. A \$50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)). 7. Your filing receipt was mailed in error because your check was returned without payment. 8. The application was filed in a language other than English. Applicant must file a verified English translation of the application, the \$130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)). 9. OTHER:
Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

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Customer Service Center Initial Patent Examination Division (703) 308-1202

FORM PTO-1533 (REV. 9/98)

U.S. GPO: 1998-446-824



APPLICATION NUMBER

09/388,294



FIRST NAMED APPLICANT

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NOTICE TO FILE MISSING PARTS OF APPLICATION Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of \$65.00 for a small entity in compliance with 37 CFR 1.27, or \$130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.

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☐ The statutory basic filing fee is: ☐ missing. ☐ insufficient. Applicant must submit \$ 100
The following additional claims fees are due: State
 ∃ The oath or declaration: ∃ Is missing or unsigned. ☐ does not cover the newly submitted items. An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required. ☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47. A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
5. The signature of the following joint inventor(s) is missing from the oath or declaration: An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted
inventor(s), identifying this application by the above Application Number and Filing Date, is required. 6. A \$50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)). 7. Your filing receipt was mailed in error because your check was returned without payment. 8. The application was filed in a language other than English. Applicant must file a verified English translation of the application, the \$130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)).
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PATENT APPLICATION FILING ACKNOWLEDGMENT

Mailing Date	9/1/99				
File No.:	19744P-000300	Attor	• •	JMH:kah	1
Inventor(s):	MICHAEL A	. EVANS et al.			
Title:	METHODS A	AND APPARA SMAIL LABI	rus fo EL#EI	OR ACCES 265824120	SSING AND 6US
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MISSING PART TRANSMITTAL Mailing Date: FILING ACKNOWLEDGMENT Appln. No. 11/22/99 File No.. 09/388,294 Inventor(s): 19744P-000300 Title: MICHAEL A. EVANS et al. Please stamp the date of receipt of the enclosed documents and return this card to addressee X. MISSING PARTS TRANSMITTAL - IN DUPLICATE;
X. INFORMATION DISCLOSURE STATEMENT & 1449 W/17 REFS. DUE DATE: DATE MAILED 11/21/99 (SUNDAY) NOV 2 6 1999 PATENT &

Customer No. 20350 TOWNSEND and TOWNSEND and CREW D Two Embarcadero Center, 8th Floor MAR 0 5 2002 San Francisco, California 94111-3834 (415) 576-0200

ASSISTANT COMMISSIONER FOR PA **BOX PATENT APPLICATION** Washington, D.C. 20231

Sir:

Transmitted herewith for filing under 37 CFR 1.53(b) is the

[X] patent application of

[] continuation patent application of divisional patent application of

[] continuation-in-part patent application of

Attomey Docket No	19744P000300US
"Express Mail" Label No	EL265824126US
Date of Deposit:	September 1, 1999

I hereby certify that this is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above, addressed to:

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COPY OF PAPERS ORIGINALLY FILED

Inventor(s)/Applicant Identifier: MICHAEL A. EVANS et al.

For: METHODS AND APPARATUS FOR ACCESSING AND TREATING BODY LUMENS ELZBSBZ47ZBUS

Enc	losed	are:

[X]_ page(s) of specification

[X] 06 page(s) of claims [X]_ page of Abstract

[X] 19 sheet(s) of [] formal [X] informal drawing(s).

[X]A [] signed [X] unsigned Declaration. []

> In view of the Unsigned Declaration as filed with this application and pursuant to 37 CFR §1.53(f), Applicant requests deferral of the filing fee until submission of the Missing Parts of Application.

> > DO NOT CHARGE THE FILLING FEE AT THIS TIME.

Telephone:

(415) 576-0200

Facsimile:

(415) 576-0300

JAMES M. HESLIN

Reg. No.: 29,541

Attorneys for Applicant

PA 3019038 v1

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PTO-103X (Rev. 6-99) FILING RECEIPT MAR 0 5 2002 E

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APPLICATION NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTORNEY DOCKET NO. | DRWGS | TOT CL | IND CL | 09/388,294 | 09/01/99 | 3732 | \$1,087.00 | 197449000300 | 19 | 93 | 4

020350 TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO CA 94111

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be instifled as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to this Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your riply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

MICHAEL A. EVANS, PALO ALTO, CA; DENIS M. DEMARAÍS, SAN JOSE, CA.

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 09/20/99 ** SMALL ENTITY ** TITLE
METHODS AND APPARATUS FOR ACCESSING AND TREATING BODY LUMENS

PRELIMINARY CLASS: 606

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TEAM: 06 DATE: 12/03/99

DATA ENTRY BY: THOMAS, SHEILA

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Applicant(s)

MICHAEL A. EVANS, PALO ALTO, CA; DENIS M. DEMARAIS, SAN JOSE, CA.

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 09/20/99
TITLE
METHODS AND APPARATUS FOR ACCESSING AND TREATING BODY LUMENS

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Firm and	Townsend and	ownsend and	Crew LLF			
Individual name	Lynn M. Thomps	ion		Reg. No	. 47,991 ————	
Signature	Tyn	n H	ron	pson		
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**ptember 1, 1999

**Struction

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**Tog Application

** **Application No.:** Carolyn Brown Supervisory Legal instrument Examiner Filing Date: **Group 3700** Title: Direct to: Box Reconstruction United States Patent and Trademark Office Washington, DC 20231 NOTICE UNDER 37 CFR 1.251 - Pending Application Statement (check the appropriate box): The copy submitted with this reply is a complete and accurate copy of applicant's record of all of the correspondence

between the Office and the applicant for the above-identified application (except for U.S. patent documents), and applicant is not aware of any correspondence between the Office and applicant for the above-identified application that is not among applicant's records.

The copy of the paper(s) listed in the notice under 37 CFR 1.251 is/are a complete and accurate copy of applicant's record of such paper(s).

The papers produced by applicant are applicant's complete record of all of the correspondence between the Office and the applicant for the above-identified application (except for U.S. patent documents), and applicant is not aware of any correspondence between the Office and the applicant for the above-identified application that is not among applicant's records.

Applicant does not possess any record of the correspondence between the Office and the applicant for the above-identified application.

Lynn M. Thompson

Typed or printed name

A copy of this notice should be returned with the reply.

Burden Hour Statement: This collection of information is required by 37 CFR 1.251. The information is used by the public to reply to a request for copies of correspondence between the applicant and the USPTO in order to reconstruct an application file. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This form is estimated to take 60 minutes to complete. This time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Page ART SEARCHES, J. C.

Telephone

PATÈNI & TRADEMARK SEARCHES AND RELATED SERVICES Crystal Towers North, Suite No. 1 1600 S. Eads Street Arlington, Virginia 22202-9296 U.S.A.

Fax 800-369-1424 703-521-6503

800-369-1422 703-521-6500

> email: tommyf@priorart.com http://www.priorart.com

August 17, 2001 USPTO



hompson Townsend and Townsend and Crew, LLP Second Floor 379 Lytton Avenue Palo Alto, CA 94301-1431

RE:

S/N 09/388,294 - RETURN OF PAPERS

YOUR REF: 19744P-000300US

PAS NO: 01-17163

Dear Lynn:

As authorized by your FedEx letter of August 8, 2001, the materials related to the above application has been hand delivered directly to the Examiner David Shay of group 330 of the USPTO on August 16, 2001.

Kindly find enclosed a postcard that has been initialed by the Examiner David Shay to indicate receipt.

Kindly call if you have a question

U.S. PATENT OFFICE

Please stamp the date of receipt of the following documents

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DAVID SHAY

Serial No:

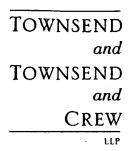
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Atty. File No. 19744P-000300US





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379 Lytton Avenue Palo Alto California 94301-1431 Tel 650 326-2400 Fax 650 326-2422

Direct: 650-324-6349 Imthompson@townsend.com

August 7, 2001

VIA FEDEX

Tommy L. Foster PRIOR ART SEARCHES Crystal Towers North, Suite 1 1600 S. Eads Street Arlington, VA 22202

Re:

US Patent Application No. 09/388,294

For: METHODS AND APPARATUS FOR ACCESSING AND TREATING

BODY LUMENS

Filed: September 1, 1999

Our File No.: 19744P-000300US

Dear Tommy,

Please find enclosed an Office Action and coverletter for Examiner David Shay, Group 330. Please hand deliver to Mr. Shay at the United States Patent and Trademark Office.

Should you have any questions regarding this request, please do not hesitate to contact me. Thank you for your assistance in this matter.

Sincerely,

Lypn M. Thompson

Patent Agent

LMT

Enclosures

- Coverletter
- Office Action directed to 09/388,294

cc: MDB PA 3162015 v1 TOWNSEND and TOWNSEND and CREW

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San Francisco, California Tel 415 576-0200

Seattle, Washington Tel 206 467-9600

Walnut Creek, California Tel 925 472-5000 Palo Aito

379 Lytton Avenue Palo Alto California 94301-1431 Tel 650 326-2400 Fax 650 326-2422

Direct: 650-324-6349 Imthompson@townsend.com

August 7, 2001

VIA HAND DELIVERY

David M. Shay Primary Examiner Group 330 Commissioner of Patents and Trademarks Washington, D.C. 20231

Re: Return of Papers (Do Not File)

Dear Mr. Shay,

We have received an Office Action, mail date 06/13/01, from you in regards to Application No. 09/388,294. However, all documents other than the coversheet are not relevant to the above named application. The documents appear to be an Office Action for Application No. 09/388,924 which is unrelated to our client. We assume that the correct documents for our client were sent to another party, a breach of confidentiality that highly concerns us.

Enclosed is the subject Office Action as received by us. We have not made any copies of the enclosed documents for our files. We would like you to provide the correct Office Action for this application with a new period for reply as we will not be able to prepare a response until receipt of the correct Office Action.

Sincerely,

Lorin M. Thornpson

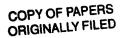
Patent Agent

LMT

Enclosure:

-Office Action directed to 09/388,294

cc: MDB PA 3162012 v1





UNITED STATES PATENT AND TRA

Mailing Date: March 29, 2001

Via First Class Mail

Application of: Evans et al.

THE CHILLIAN TO STORY OF THE PARTY OF THE PA Title: METHODS AND APPARATUS FOR ACCESSING AND TREATING BODY LUME

Serial No.:

09/388,294

Filed: September 1, 1999

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- Transmittal Letter Amendment
- 2. Fee Transmittal
- Petition for Extension of Time 3.
- Amendment

File No. 19744P-000300US

Atty/Secty: LMT/lah

UNITED STATES PATENT AND TRADEMARK OFFICE

Via First Class Mail

Title: METHODS AND APPARATUS FOR ACCESSING AND TREATING BODY LUMENS Mailing Date: March 29, 2001

Serial No.:

09/388,294

Please stamp the date of receipt of the enclosed documents and return this card to addressee:

Transmittal Letter - Amendment

APR 0 9 2001

Fee Transmittal 2.

Petition for Extension of Time

3. Amendment

File No. 19744P-000300US

Atty/Secty: LMT/lah



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and Individual name	Lyn	n M. Thompson			Reg No	. 47,991		
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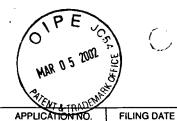
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FEE TO A NOMITTAL	Complete if Known					
FEE TRANSMITTAL	Application Number	09/388,294				
∕o\PE 2001	Filing Date	September 1, 1999				
MAR 0 5 2002 Pater lees are subject to annual revision.	First Named Inventor	EVANS, MICHAEL, et. al.				
MAR Pater lees are subject to annual revision.	Examiner Name	SIRMONS, K.				
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TOTAL PAYMENT (\$) 190	Attorney Docket No.	19744P000300				

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SUBMITTED BY				c	omplete (if applicable)	
Name (Print/Type)	Lynn M. Thompson	Registration No. (Attorney/Agent)	47,991	Telephone	650-326-2400	
Signature	Fym	Thompson		Date	3/28/01	
						

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FIRST NAMED INVENTOR

ATTORNEY DOCKET NO.

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ART UNIT

PAPER NUMBER

2763

DATE MAILED:

12/01/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Kesponse Due___X

Application No. Applicant(s)

09/388,294

Michael Evans

Examiner

Kevin C. SIrmons

Group Art Unit 3763

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	ANT THE WAY THE WAY BY THE P
X Responsive to communication(s) filed on Sep 18, 2000	
☐ This action is FINALE.	
Since this application is in condition for allowance except for formal matters, in accordance with the practice under Ex parte Quay/035 C.D. 11; 453 O.G. 213.	ed
A shortened statutory period for response to this action is set to expire3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).	3
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Application Papers See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on is/are objected to by the Examiner.	
☐ The proposed drawing correction, filed on is ☐ approved ☐disapproved.	
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
Acknowledgement is made of a claim for foreign priority under 33 5.3.5. § 113(a)-(d). [] All _Some* None of the CERTIFIED copies of the priority documents have been	
received.]
received in Application No. (Series Code/Serial Number)	
received in this national stage application from the International Bureau (PCT Rule 17.2(a)).	
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).	
☐ Interview Summary, PTO-413	
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

FO	RM P	TO-892 O P E 2012 P	DEPARTMENT AND TRA	IT OF COMMERCE ADEMARK OFFICE	SERIAL NO. 09388294	GROUP ART UNIT 3763	ATTACHME TO PAPER		7
		NOTICE OF RI	ERENCE	S CITED	APPLICANT(S)	Michael Ev	rans		
	<u>_</u>			U.S. PATENT DO	CUMENTS	• *** •			
*		DOCUMENT NO.	DATE	NA	ME	CLASS	SUB- CLASS	FILI DA	NG TE
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Page 2

Application/Control Number: 09388294

Art Unit: 3763

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 33, it is unclear if the means advancable from the catheter for creating a second access penetration is the guide tube or the penetrating element or both.

As to claim 43, it is unclear as to what is meant by the guide tube has a pre-formed tip which deflects laterally. It appears that the penetrating element has the pre-formed tip. Please explain?

Note: The examiner will examine the claims as best understood.

Claim Rejections - 35 USC § 102

- 2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
 - (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
- 3. Claims 33, 34, 36, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Quick et al. U.S. Pat. No. 5,857,999.

Application/Control Number: 09388294

Art Unit: 3763

Quick discloses a device for positioning a filament in a body lumen comprising: a catheter (10) which can be introduced through a first access penetration into the body lumen; and means advancable from the catheter (12, 70) for creating a second access penetration and providing a filament path (12, 70) between said first and second access penetrations; wherein the catheter has at least one lumen therethrough (10) and the advancable means is reciprocatable received in the catheter lumen (10); wherein the advancable means comprises a guide tube having a lumen therethrough (12) and a penetrating element removably received in the lumen and extending from the distal tip of the guide tube (70, 98), wherein the penetrating means can be withdrawn from the guide tube after the guide tube has been placed between the access penetrations to leave the guide tube lumen as the filament path (figs. 1-3; further comprising an expandable anchor disposed over at least a position of the catheter (64)).

4. Claims 33-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Tafeen. U.S. Pat. No. 3,539,034.

Tafeen discloses a device for positioning a filament in a body lumen comprising: a catheter (20) which can be introduced through a first access penetration into the body lumen; and means advancable from the catheter (12, 14, 16, 18) for creating a second access penetration and providing a filament path (12, 14, 16) between said first and second access penetrations; wherein the advancable means has a pre-formed tip which deflects laterally as it is advanced from the catheter (12, 14, 16, 26); wherein the advancable means comprises a guide tube (16) having a lumen therethrough and a penetrating element removably received in the lumen (12, 14, 18),

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Art Unit: 3763

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wherein the penetrating element can be withdrawn from the guide tube after the guide tube has ben placed between the access penetration to leave the guide tube lumen as the filament path (12, 14); wherein the penetrating element is a stylet (12, 14, 18).

5. Claims 42- 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. U.S. Pat. No. 5,246,014.

Williams discloses a device for positioning a filament in a body lumen, said device comprising: a catheter which can be introduced through a first access penetration into the body lumen, said catheter having a proximal end, distal end and a lumen therethrough (50); a guide tube reciprocatably disposed in the lumen of the catheter so that the guide tube can be advanced from the distal end of the catheter (40), said guide tube having a proximal end, a distal end, and a lumen therethrough (40), wherein the distal end of the guide tube is deflectable (col. 16, lines 1 and 2); and a penetrating element reciprocatably mounted in the lumen of the guide tube so that the penetrating element can be advanced from the distal end of the guide tube to penetrate a luminal wall in a direction determined by deflection of the distal end of the guide tube (10); wherein the guide tube has a pre-formed tip which deflects laterally as the guide tube is advanced from the catheter (40 and 10); wherein the penetrating element is a stylet (10); further comprising an expandable anchor disposed over at least a portion of the catheter (10).

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Art Unit: 3763

Response to Arguments

Applicant's arguments with respect to claims 33-38 and 42-45 have been considered but 6. are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410.

The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons

Patent Examiner

11/28/00

RICHARD K. SEIDEL

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 3700



AMENDMENT FILING ACKNOWLEDGMENT

Mailing Date:

9/12/00

Appln. No.

09/388,294

File No.:

15471-000300

Inventor(s): Title:

MICHAEL A. EVANS, et al.

Attorney: JMH/lmc METHODS AND APPARATUS FOR ACCESSING AND TREATING...

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AMENDMENT TRANSMITTAL

AMENDMENT (5 pages)

DUE DATE: DATE MAILED 11/11/00 9/12/00

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ATTORNEY DOCKET NO.

09/388,294

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FIRST NAMED INVENTOR

TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER

EIGHTH FLOOR

SAN FRANCISCO CA 94111

EXAMINER

SIRMONS,K

ART UNIT PAPER NUMBER

3763 5

DATE MAILED:

08/11/00

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Commissioner of Patents and Trademarks

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Application No. 09/388,294 Applicant(s)

• •

Examiner

Kevin C. Sirmons

Group Art Unit 3763

Michael Evans

Responsive to communication(s) filed on <u>Sep 1, 1999</u>					
This action is FINAL.	•				
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/1835 C.D. 11; 453 O.G. 213.					
A shortened statutory period for response to this action is set to expire3month(s), or thirty longer, from the mailing date of this communication. Failure to respond within the period for response vapplication to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the part of 1.136(a).	will cause the				
Disposition of Claim					
	e pending in the applicat				
Of the above, claim(s) 1-31, 40, and 41 is/are with	drawn from consideration				
☐ Claim(s)	_ is/are allowed.				
	_ is/are rejected.				
☐ Claim(s)	is/are objected to.				
☐ Claims are subject to restrictio	_				
Application Papers					
∑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.					
☐ The drawing(s) filed on is/are objected to by the Examiner.					
☐ The proposed drawing correction, filed on is ☐ approved ☐ disappro	ved.				
☐ The specification is objected to by the Examiner.					
☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. § 119					
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).					
☐ All ☐Some* None of the CERTIFIED copies of the priority documents have been					
☐ received.					
received in Application No. (Series Code/Serial Number)					
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).				
*Certified copies not received:					
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
Attachment(s)					
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☐ Interview Summary, PTO-413 ☑ Notice of Draftsperson's Patent Drawing Review, PTO-948					
☐ Notice of Informal Patent Application, PTO-152					
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SEE OFFICE ACTION ON THE FOLLOWING PAGES					

Application/Control Number: 09388294

Art Unit: 3763

Drawings

DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to a method for forming a second access penetration in a wall of a body lumen having a first access penetration in said wall, classified in class 604, subclass 28.
 - II. Claims 10-32, drawn to a method for positioning a guidewire in a body lumen, classified in class 604, subclass 500.
 - III. Claims 33-39, drawn to a device for positioning a filament in a body lumen, classified in class 604, subclass 164.01.
 - IV. Claims 40-41, drawn to a kit, classified in class 206, subclass 570.
- 2. The inventions are distinct, each from the other because of the following reasons:

 Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination already has two separate access sites formed in the wall. The subcombination has separate utility such as forming a second access in a wall.

Page 3

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Drawings

- 3. Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced by a gastronomy device.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. During a telephone conversation with Jim Heslin on 8/3/00 a provisional election was made without traverse to prosecute the invention of group III, claims 33-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-32 and 40-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Page 4

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Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "support tube" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 33-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 33 and 39, it is unclear what is the structural difference between the catheter and the support tube. They appear to be the same!

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Miraki U.S. Pat. No. 5,387,193.

Application/Control Number: 09388294

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Drawings

Miraki discloses a device for positioning a filament in a body lumen comprising: a catheter (10) which can be introduced through a first access penetration into the body lumen; and means advancable from the catheter (84) for creating a second access penetration and providing a filament path (84) between said first and second access penetrations; wherein the catheter has at least one lumen therethrough (112) and the advancable means is reciprocatable received in the catheter lumen (112); wherein the advancable means has a preformed tip which deflects laterally as it is advanced from the catheter (84); wherein the advancable means comprises a guide tube having a lumen therethrough (110) and a penetrating element removable received in the lumen and extending from the distal tip of the guide tube, wherein the penetrating means can be withdrawn from the guide tube after the guide tube has been placed between the access penetrations to leave the guide tube lumen as the filament path wherein the penetrating element is a stylet (84); further comprising an expandable anchor disposed over at least a position of the catheter (48); further comprising a support tube having a lumen (9 and 11).

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410.

The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Application/Control Number: 09388294

Art Unit: 3763

Drawings

Kevin C. Sirmons

Patent Examiner

8/7/00

Sharon Kennedy Sharon Kennedy Primary Examiner

Application No.: 09/388,294 Attorney Docket No.: 19744P000300 FORM PTO-1449 (Modified MAR 0 5 2002 Applicant: MICHAEL A. EVANS et al. LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLASURE STATEMENT (Use several sheet in the cessary) Group: 3732 Filing Date: September 1, 1999 Page 1 U.S. PATENT DOCUMENTS Filing Date Reference Designation Sub-class Class Name (If Appropriate) Date Document No. Examiner Initial Forgarty 11/11/1986 4,621,636 Α Ginsburg et al. 07/05/1988 4,754,752 В Ginsburg et al. 09/06/1988 4,769,005 C Ginsburg et al. 12/13/1988 4,790,310 D Ginsburg 04/30/1991 5,011,488 E 02/22/1994 Wilk 5,287,861 F Wilk 04/25/1995 5,409,019 G Goy 05/09/1995 MON S & 1838 5,413,581 H Wilk 07/04/1995 5,429,144 I Venbrux 08/22/1995 5,443,497 J Faxon et al. 11/07/1995 5,464,395 K 10/17/1989 Ginsburg 4,873,978 L 06/16/1998 Trerotola 5,766,191 M Cox et al. 10/20/1998 5,824,040 N Claren et al. 05/04/1999 O 5,899,909 FOREIGN PATENT DOCUMENTS Translation Sub-class Class Country (Yes/No) Date Document No. **PCT** 04/17/1997 WO 97/13463 P 04/17/1997 **PCT** WO 97/13471 Q OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.) DATE CONSIDERED **EXAMINER**

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No



The drawing(s) filed (insert date) 1/9/9 are:

A. approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be sumitted according to the instructions on the back of this notice.

	i
DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:	8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
Black ink. Color.	Words do not appear on a horizontal, left-to-right fashion
Color drawings are not acceptable until petiton is granted.	when page is either upright or turned so that the top
Fig(s)	becomes the right side, except for graphs. Fig(s)
Pencil and non black ink not permitted. Fig(s)	9. SCALE. 37 CFR 1.84(k)
2. PHOTOGRAPHS. 37 CFR 1.84 (b)	Scale not large enough to show mechanism without
1 full-tone set is required. Fig(s)	crowding when drawing is reduced in size to two-thirds in
Photographs not properly mounted (must use brystol board or	reproduction.
photographic double-weight paper). Fig(s)	Fig(s)
Poor quality (half-tone). Fig(s)	10. CHARACTER OF LINES, NUMBERS, & LETTERS.
3. TYPE OF PAPER. 37 CFR 1.84(e)	37 CFR 1.84(i)
Paper not flexible, strong, white, and durable.	Lines, numbers & letters not uniformly thick and well
Fig(s)	defined, cloan, durable, and black (poor line quality).
Erasures, alterations, overwritings, interlineations,	Fig(s) // (11. SHADING. 37'CFR 1.84(m)
folds, copy machine marks not accepted. Fig(s)	Solid black areas pale. Fig(s)
Mylar, velum paper is not acceptable (too thin).	Solid black shading not permitted. Fig(s)
Fig(s)	Shade lines, pale, rough and blurred. Fig(s)
4. SIZE OF PAPER. 37 CFR 1.84(1): Acceptable sizes:	12. NUMBERS, LETTERS, & REFERENCE CHARACTERS.
21.6 cm by 27.9 cm (B 1/2 x 11 inches)	37 CFR 1.84(p)
All drawing sheets not the same size.	Numbers and reference characters not plain and legible.
Sheet(s)	Fig(s)
Drawings sheets not an acceptable size. Fig(s)	Figure legends are poor. Fig(s)
5. MARGINS. 37 CFR 1.84(g): Acceptable margins:	Numbers and reference characters not oriented in the
	same direction as the view. 37 CFR 1.84(p)(1)
Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm	Fig(s)
SIZE: A4 Size	English alphabet not used. 37 CFR 1.84(p)(2)
Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm	Figs
SIZE: 8 1/2 x 11	Numbers, letters and reference characters must be at least
Margins not acceptable. Fig(s)	.32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3)
Top (T) Left (L)	Fig(s)
Right (R) Bottom (B)	13. LEAD LINES. 37 CFR 1.84(q)
6. VIEWS. 37 CFR 1.84(h)	Lead lines cross each other. Fig(s)
REMINDER: Specification may require revision to	— Lead lines missing. Fig(s)
correspond to drawing changes.	14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(I)
Partial views. 37 CFR 1.84(h)(2)	Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s)
Brackets needed to show figure as one entity.	15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
Fig(s)	Views not numbered consecutively, and in Arabic numerals,
	beginning with number 1. Fig(s)
Fig(s) Enlarged view not labeled separetely or properly.	16. CORRECTIONS. 37 CFR 1.84(w)
Fig(s)	Corrections not made from prior PTO-948
7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)	dated
Hatching not indicated for sectional portions of an object.	17. DESIGN DRAWINGS. 37 CFR 1.152
Fig(s)	Surface shading shown not appropriate. Fig(s)
Sectional designation should be noted with Arabic or	Solid black shading not used for color contrast.
Roman numbers. Fig(s)	Fig(s)
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COMMENTS	
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	F	5,814,058	9/1998	Carlso	n et al	606	185		·
	G	5,830,125	11/1998	Scribne	er et al	606	139		
	н	5,885,238	3/1999	Steven	s et al	604	4		-11
	ı	5,916,193	6/29/99	Steven	s et al	604	4		
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT

Attorney Docket No.: 19744P-000300

Assistant Commissioner for Patents,

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Washington, D.C. 20231, on NOVEMBER 22, 1999

TOWNSEND and TOWNSEND and CREW LLP

By Karen A Hallock

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MICHAEL A. EVANS et al.

Application No.: 09/388,294

Filed: September 1, 1999

For: METHODS AND APPARATUS FOR

ACCESSING AND TREATING

BODY LUMENS

Examiner: Not Assigned

Art Unit: 3732

TRANSMITTAL LETTER - RESPONSE

TO NOTICE OF MISSING PARTS

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Assistant Commissioner for Patents

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Sir:

Pursuant to the Notice to File Missing Parts of Application - Filing Date Granted dated September 21, 1999, enclosed are the following to be made of record in the above-identified application:

- 1. Executed Declaration;
- 2. Executed Power of Attorney by Assignee;
- 3. Executed Small Entity Declaration
- 4. Information Disclosure Statement & 1449 w/17 refs.; &
- 5. Return copy of Notice.